

Applicant is entitled. These claim amendments were not made earlier because Applicant believes the originally submitted claims are patentable over the Office's citations. Further, these amendments do not raise new issues, but rather more concisely recite Applicant's claimed invention, as originally filed. Applicant reserves the right to prosecute any amended (or presently unclaimed) subject matter in a continuing or divisional application.

Administratively, Applicant simultaneously files a Small Entity Petition for Extension of Time (along with payment of all requisite Extension Fees due), requesting the Office grant Applicant's Petition for response within the third month, ending January 25, 2004, following expiration of the shortened statutory period for response on October 25, 2003. In addition, Applicant contemporaneously submits, under separate cover addressed to Mail Stop: ASSIGNMENT RECORDATION SERVICES, an Assignment of Applicant's rights in, *inter alia*, this Application.

As a preliminary matter, Applicant submits along with this Amendment, an Information Disclosure Statement (along with payment of any requisite fee due), and completed PTO Form-1449, citing all references originally cited in the application, as filed, along with additional references identified in a recent updated search undertaken by Applicant's undersigned representative.

Upon receipt of the Office's written approval of the proposed corrections to drawings, and upon the Office's indication of allowable subject matter in this Application, formal drawings will be corrected and timely filed prior to payment of the Issue Fee.

Applicant acknowledges the Office's allowance of Claims 15-20; but, however, respectfully submits that, in view of the foregoing amendments and Remarks herein, all presently pending claims of this application are allowable.

The Action rejected Claim 6 under 35 U.S.C. §112. Claim 6 is amended, reciting "the placement means", for which sufficient antecedent basis exists. Applicant respectfully requests the Office's reconsideration and withdrawal of the rejection.

In the Action, the Office rejected Claims 1-14 under 35 U.S.C. §102(e) over U.S. Patent No. 5,954,671 to O'Neill (O'Neill '671). Although Applicant respectfully disagrees with the Office's rejection, to expedite prosecution, Applicant has amended independent Claim 1 to more concisely and particularly recite Applicant's presently claimed invention.

O'Neill '671 discloses a bone harvesting apparatus and method. Specifically, the bone harvesting apparatus comprises a guide wire 10, an obturator 20, at least one dilator 30, a forked cannula 40, and a cutter cylinder 50 attached to a T-handle 70 (col. 4, lines 10-20, *et seq.*). O'Neill '671 more specifically discloses that an operator (presumably a surgeon or similarly skilled medical professional) places the obturator 20 over a previously positioned guide wire 10. Following that, the operator places one or more dilators 30 over the obturator, incrementally, further splitting tissue with each dilator of increasing diameter. After setting the dilator(s), the operator places a forked cannula 40 over the previously, successively positioned dilator(s) 30, obturator 20 and guide wire 10, and subsequently removes the guide wire 10, obturator 20, and possibly, dilator(s) 30, providing a working channel for a cutter cylinder 50, attached to a T-handle 70. (See, for example, col. 6, lines 10-62, and Figure 7.)

O'Neill '671 does not disclose a biopsy/access tool, as recited in Claim 1-14, more particularly, a biopsy device and a cannula, at least removably coupled to a handle means, wherein if the handle means is separated from the biopsy device, at least a portion of a first functional channel telescopes over the biopsy device, recited in Claim 1, from which all Claims 2-14 ultimately depend (emphasis added). Indeed, O'Neill '671 discloses exactly the opposite of Applicant's claimed invention, teaching well away from Applicant's inventive biopsy/access tool. O'Neill '671's cutting cylinder 50 possesses none of the physical or functional attributes of any element of Applicant's claimed invention, but instead, must work within a channel created by successive "obturation and dilation(s)" steps. An O'Neill '671 apparatus would not only be

impractical, but entirely unsuitable for surgical procedures requiring an acutely efficient and expeditious surgical technique, employing a highly specialized biopsy/access tool, such as instantly claimed, and as recited in allowed method Claims 15-20: first positioning a biopsy device, and second, subsequently telescoping an access cannula over the biopsy device. In distinct contrast to O'Neill '671, Applicant's tool recited in Claims 1-14, by conscious design, does not recite several superfluous, indispensable O'Neill '671 apparatus components: including, *inter alia*, the obturator 20 and dilator(s) 30, in the absence of which, the O'Neill '671 apparatus would not function as disclosed. In view of O'Neill '671's very limited disclosure, and disparate teaching, Applicant respectfully submits that Applicant's presently claimed invention is novel, and requests that the Office reconsider and withdraw this rejection.

Furthermore, because O'Neill '671 teaches exactly the opposite of Applicant's claimed invention, there is no suggestion in O'Neill '671 to disregard O'Neill '671's disparate disclosure to obtain Applicant's invention, particularly, that recited in Applicant's Claim 1, which, as well as Claims 2-14, is unobvious in view of the applied O'Neill '671 reference.

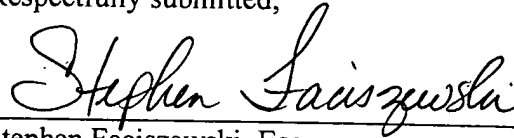
The Action also rejected Claims 3 and 9, under 35 U.S.C. §103(a), being unpatentable (obvious) over the O'Neill '671 disclosure. Applicant respectfully disagrees. As Applicant presents above, Applicant's invention of at least Claim 1 is both unanticipated, and unobvious, in view of O'Neill '671's entire disclosure, therefore obviating the basis upon which the Office applies this rejection to Claims 6 and 9. Applicant therefore respectfully submits that Claims 3 and 9, as well, are unobvious, over O'Neill '671, and requests that the Office reconsider and withdraw this rejection.

In view of the foregoing Amendment and Remarks, Applicant submits that Claims 1-20, presently pending in the application, are in condition for allowance and patentably distinguish over the references applied and of record. Applicant solicits the Office's prompt issuance of an early notice of allowance.

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Should the Office have any questions concerning this communication, deems a personal interview helpful, or identifies any additional fees to maintain this pending application, which Applicant has not contemporaneously or previously paid, Applicant asks that the Office promptly telephone Applicant at 715.389.2619; or alternatively, Applicant's undersigned Attorney's U.S. phone number: 206.283.1665.

Respectfully submitted,



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Date: January 21, 2004

SEPARATE VERSION OF REWRITTEN CLAIMS

UNDER 37 C.F.R. §1.121(c)(i)

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1. (Currently Amended) An integrated biopsy/access tool for harvesting a biopsy specimen and providing access to a remote anatomical site, comprising:
    - a. a biopsy device having distal and proximal ends;
    - b. a cannula having distal and proximal ends, and a first functional channel extending therebetween; and
    - c. a handle means, removably coupled to at least [one of] the [biopsy device and] cannula, wherein if the handle means is separated from said biopsy device, at least a portion of the first functional channel [is capable of telescoping] telescopes over the biopsy device.
  2. (Original) A tool according to claim 1 wherein, when:
    - a. the cannula distal end is disposed relative to the biopsy specimen or anatomical site; and
    - b. the biopsy device is advanced within said first functional channel such that a handle distal end engages the cannula proximal end, the biopsy device distal end extends a distance beyond said cannula distal end, thereby securing a biopsy specimen.
  3. (Original) The tool according to claim 1, wherein the biopsy device has an outer dimension ranging from 2 to 3 millimeters, and the cannula has an outer dimension between 3 and 4 millimeters.
  4. (Original) The tool according to claim 1, further comprising a placement means for determining proper placement of at least one of the biopsy device and cannula.
  5. (Original) The tool according to claim 4, wherein the handle means is further removably coupled to the placement means.
  6. (Currently Amended) The tool device according to claim 4, wherein the placement [device] means is telescopically received within a second functional channel extending through the biopsy device.
  7. (Original) The tool according to claim 4, wherein the placement means comprises a trocar.
  8. (Original) The tool according to claim 7, wherein the trocar has a tapered distal end.
  9. (Original) The tool according to claim 8, wherein the trocar has an outer diameter between about 2 and 3 millimeters.

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10. (Original) The tool according to claim 8, wherein the trocar has a channel extending therethrough.
  11. (Original) The tool according to claim 4, wherein the placement means comprises a guide wire.
  12. (Original) The tool according to claim 4, wherein the placement means comprises a linear scale on at least one of the biopsy device and cannula for measuring a penetration depth that the biopsy/access tool is positioned at the remote anatomical site.
  13. (Original) The tool according to claim 1, wherein:
    - a. the biopsy device has at least one demarcation axially spaced thereon;
    - b. when the cannula distal end is disposed relative to the biopsy specimen or anatomical site; and
    - c. when the biopsy device is advanced through the first functional channel so as to align a demarcation with the cannula proximal end;
      - i) then, the biopsy device distal end extends a predetermined distance beyond said cannula distal end, thereby securing the biopsy specimen.
  14. (Original) The tool according to claim 1, wherein the handle means simultaneously couples with the distal ends of the biopsy device and cannula.
  15. (Original) A method for obtaining a biopsy specimen and accessing a remote anatomical site, comprising the steps of:
    - a. placing a biopsy device at an anatomical site;
    - b. advancing a cannula over the biopsy device;
    - c. securing the biopsy specimen; and
    - d. withdrawing the biopsy device containing the biopsy specimen from the remote anatomical site, thereby providing access through the cannula to the remote anatomical site.
  16. (Original) The method according to claim 15, further comprising the step of positioning a placement means at the remote anatomical site prior to placing the biopsy device.
  17. (Original) The method according to claim 15, wherein advancing the cannula comprises the steps of:
    - a. coupling a handle means to a cannula; and

- b. sliding the cannula coupled to the handle telescopically over the biopsy device.
18. (Original) The method according to claim 15, wherein securing the biopsy specimen comprises the steps of:
- a. coupling a handle means to the biopsy device;
  - b. advancing the biopsy device; and
  - c. fixing a biopsy specimen in the biopsy device with a securing means.
19. (Original) The method according to claim 18, wherein the securing means severs and retains the biopsy specimen.
20. (Original) The method according to claim 15, further comprising introducing at least one of medicaments, delivery cannula, tissue modification devices, catheters, tubes, diagnostic instruments, and pharmaceuticals and therapeutic agents.
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